

*U.S. Patent Application Serial No. 10/581,628*

*Amendment dated December 1, 2011*

*Reply to Office Action of July 5, 2011*

**REMARKS**

Applicant respectfully requests entry of the Amendment and reconsideration of the claims. After entry of the Amendment, claims 1 and 3-27 will be pending. Claim 2 has been incorporated into the claim 1. Claims 25-27 are newly presented.

The Amendment is supported throughout the specification, including for example at page 7, lines 9-11 and 17-19, and does not introduce new matter.

The Declaration of Carsten Andersen under 37 C.F.R. § 1.132 filed with the previous response contained an unintentional and obvious typographical error in paragraph 16. The last line in paragraph 16 should read “mixing the nicotine with the cation exchange resin prior to the polyol” instead of “mixing the nicotine with the polyol prior to the cation exchange resin”. This error is obvious in view of the description of the invention in the specification and paragraph 7 in the Declaration which clearly show that the nicotine is combined with the cation ion exchange resin before the polyol is added. A corrected version of Mr. Andersen’s Declaration under 37 C.F.R. § 1.132 is filed herewith to correct the unintentional and obvious typographical error in paragraph 16.

**Rejection under 35 U.S.C. § 112**

Claims 1-2 and 22-24 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claim 2 has been incorporated into claim 1. The rejection is therefore addressed insofar as it applies to claims 1 and 22-24.

The Office Action alleges that the limitation “reaction product” in claim 1 renders claim 1 and dependent claims 2 and 22-24 indefinite. Without acquiescing to the rejection and solely for the purpose of advancing prosecution, claim 1 has been amended to recite that the nicotine delivery product comprising an intimate mixture of a nicotine/cation exchange resin complex and an organic polyol wherein the organic polyol is adsorbed to the nicotine/cation exchange resin complex. Support for the amendment can be found in the specification, for example, at page 7, lines 16-19. Applicant submits that claim 1 as amended, as well as claims 22-24 which depend from claim 1, comply with the requirements of § 112, second paragraph.

Withdrawal of the rejection is respectfully requested.

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**Rejection under 35 U.S.C. § 103**

Claims 1-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Walling (U.S. 6,586,449) in view of Ferno (U.S. 3,845,217). Applicant respectfully traverses the rejection.

The Office Action acknowledges that Walling does not disclose the specific order of method steps recited in the claims or a chewing gum. Citing MPEP 2144.04(IV)(C), the Office Action maintains that absent unexpected results the selection of any order of performing process steps is *prima facie* obvious in view of Walling. Applicants do not agree.

It is well established that "a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02 citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) *cert. denied*, 469 U.S. 851 (1984). Walling discloses that the nicotine release characteristics of a chewable smoking substitute, such as those disclosed in Ferno, are not sufficient as such gums are only marginally effective because nicotine release is small and in reduced amounts. See Walling at col. 1, lines 41-50. In order to obtain a release rate of 70% within 10 minutes, Walling discloses that it is necessary to combine the polyol with the cation exchange resin before admixture with nicotine. See col. 2, lines 56-58. Accordingly, one of skill in the art would not have been motivated to combine the cation exchange resin with nicotine before admixture with the polyol as Walling specifically teaches away from mixing the exchange resin with nicotine before admixture of the resin and polyol.

Ferno does not cure the deficiencies of Walling. Contrary to the assertions in the Office Action, there is no teaching or suggestion in Ferno that adding more nicotine to the resin would enhance the rate of nicotine release from the resin. The enhanced nicotine release is a function of the polyol. The amount of nicotine in the Walling product is already at least 50% greater than the amount of nicotine in the product disclosed in Ferno (0.1 to 10% nicotine by weight, preferably 0.5 to 2 %; col. 8, lines 56-60), so there is no motivation as alleged in the Office Action to mix the nicotine with the exchange resin (as taught by Ferno) prior to addition of the polyol.

Ferno also does not disclose or suggest that any measure which increases the nicotine content also increases the nicotine release rate. As discussed by Mr. Andersen in the Declaration, one of skill in the art would understand the passage from Ferno cited in the Office Action (Ferno at col. 3, lines 69-75) to mean that, when comparing two nicotine resin composition that differ only in nicotine content, the composition with the higher nicotine content will have the faster release. See the Declaration at paragraph 10. This general rule is based on the assumption that the nature of the binding between the nicotine and the resin is the same in the two samples. If there are multiple differences between the compositions being compared, then it is not necessarily the case that the composition with the higher nicotine content has the faster release as the other differences between the compositions may also have an impact and outweigh any effect caused by the nicotine content. See Declaration at paragraph 11.

Accordingly, an important difference between the claimed compositions and the compositions in Walling is the strength of the binding between the resin and the nicotine. When adding nicotine to the resin before polyol, the nicotine can bind strongly to the resin as there is no competition for the resin binding sites. In contrast, when polyol is allowed to bind to the resin before nicotine is introduced, then only a weaker partial binding of the nicotine is possible. A weaker binding will lead to a faster release, and this is the core teaching of Walling. See, for example, Walling at claim 1 which refers to the resin “having some of its binding sites partially blocked with said polyol” and table 2 where the mixing of a polyol and resin before binding the nicotine allows a faster release rate to be obtained. See Declaration at paragraph 12.

Therefore, one of skill in the art would not have reasonably expected that adding the polyol after mixing the nicotine with the resin would be useful for increasing nicotine release rate as this goes against the teaching of Walling which discloses that partially blocking resin binding sites with polyol is required to achieve the nicotine release rates disclosed therein. Accordingly, one of skill in the art in view of Walling would have reasonably expected that the stronger binding obtained by omitting pretreatment of the resin with the polyol would slow release, whereas Applicant surprisingly and unexpectedly observed the opposite effect. See Declaration at paragraph 13.

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The Office Action questions the significance of the difference between the 78.6% release value reported for a product produced according to the invention and the 71% value reported for the Walling products. As discussed by Mr. Anderson in the enclosed Declaration Under 37 C.F.R. § 1.132, one of skill in the art would understand and consider a difference of 7.6% to be meaningful in practice. See the Declaration at paragraph 8. Walling also considers such a result to show a surprising advantage. In Walling, the nicotine release rate for the sorbitol-containing sample was 7% greater than the nicotine release rate for the sample not containing a polyol. See tables 1 and 2 of Walling at columns 3 and 4 and the subsequent discussion in which Walling considers a difference of 7% in nicotine release rate to be significant.

The Office Action alleges that the examples provided in the declaration of Carsten Andersen under 35 CFR 1.132 filed May 26, 2011 does not support unexpected results because the results for the full scale commercial batches do not produce the claimed release rates. Applicant does not agree.

Runs A and B clearly produced a nicotine delivery product having an average nicotine release rate of at least 80%. The average nicotine release rate of the product from the full scale batches was 78.6%. However, 78.6% is within the normal fluctuation of the test method which is +/- 2% as disclosed in Walling (see Walling at col. 4, lines 33-33) and the average nicotine release rate of the product produced in Runs A and B shows that product having a nicotine release rate of at least 80% is reproducible.

In view of the foregoing, Applicant submits the Office Action has failed to establish a *prima facie* case of obviousness as Walling in view of Ferno teaches away from the claims. Therefore, absent Applicant's disclosure, one of skill in the art would not have been motivated to modify Walling in view of Ferno as alleged in the Office Action nor had a reasonable expectation of successfully arriving at the claims. The claims are also patentable over the combination of Walling and Ferno in view of the unexpected results. Withdrawal of the rejection is respectfully requested.

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**Double Patenting**

Claims 1-22 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 6, 10-15, and 19-22 of Application No. 10/921,199. Although the rejection cites Application No. 10/921,199, Applicant believes the Examiner intended to recite Application No. 11/921,199.

Applicant acknowledges the rejection and request that the rejection be held in abeyance until allowable subject matter is indicated.

If a provisional non-statutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications and the later-filed application is rejectable on other grounds, the Examiner should withdraw the provisional ODP rejection and permit the earlier filed application to issue as a patent without a terminal disclaimer. MPEP § 804(I)(B)(1). Applicant notes that the present application was filed on March 16, 2007, while copending Application No. 11/921,199 was filed on November 21, 2008. The present application is therefore the earlier filed of the two applications.

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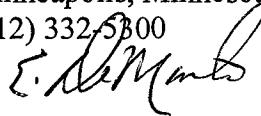
**Conclusion**

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

  
Eric E. DeMaster  
Reg. No. 55,107  
EED:jrm

Date: December 1, 2011

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